



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE

United States Patent and Trademark Office

Address: COMMISSIONER FOR PATENTS

P.O. Box 1450

Alexandria, Virginia 22313-1450

www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/572,975	05/10/2007	Anthony John Clark	9052-241	4577
20792	7590	02/18/2009		
MYERS BIGEL, SIBLEY & SAJOVEC PO BOX 37428 RALEIGH, NC 27627			EXAMINER SINGH, ANOOP KUMAR	
			ART UNIT 1632	PAPER NUMBER
			MAIL DATE 02/18/2009	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

### Office Action Summary

**Application No.**

10/572,975

**Applicant(s)**

CLARK ET AL.

**Examiner**

ANOOP SINGH

**Art Unit**

1632

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-27 and 31-40 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-27, 31-40 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF/ICE)  
Paper No(s)/Mail Date \_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_

### DETAILED ACTION

Applicants amendments to the claims filed March 22, 2006 has been received and entered. Claims 28-30 have been cancelled, while claims 34-40 have been added. Claims 1-27, 31-40 are pending in this application.

#### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, 15, 19-20, 26-27, 31-40, drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is secreted alkaline phosphatase (SEAP), a host cell comprising the nucleic acid of the invention and method of using cell for in vitro screening.

Group II, claims 1-8, 11-15, 19-20, 26-27, 31-40, drawn to drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is secreted is a modified human beta choriogonadotrophin (hCG), a host cell comprising the nucleic acid of the invention and method of using cell for in vitro screening.

Group III, claims 1-8, 15-16, 19-20, 26-27, 31-40, drawn to drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is secreted hormonal molecule FSH, a host cell comprising the nucleic acid of the invention and method of using cell for in vitro screening.

Group IV, claims 1-8, 15, 17, 19-20, 26-27, 31-40, drawn to drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is antibody is gamma or light chain (Bence Jones) protein, a host cell comprising the nucleic acid of the invention and method of using cell for in vitro screening.

Group V, claims 1-8, 15, 18, 19-20, 26-27, 31-40, drawn to a nucleic acid construct comprising a nucleic acid sequence further comprising a nucleic acid sequence encoding a reporter protein that is enzymatic molecule is feline urinary carboxylase, a host cell comprising the nucleic acid of the invention and method of using cell for in vitro screening.

Group VI, claims 21-25, 31-33, drawn to a transgenic non-human animal wherein the cells of the non-human animal express the protein or product encoded by the nucleic acid sequence of the invention, and method of using cell for in vivo screening.

The inventions listed as Groups I-VI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: The "special technical feature" is a nucleic acid encoding a reporter gene that is secretable or excretable as a protein. Jain et al (J Biol Chem. 2000; 275(35):27032-6, IDS) teach nucleic acid encoding secretable SEAP. Similarly, Bao et al (J Natl Cancer Inst. 2002 Apr 3;94(7):522-8, IDS) teach a construct in which a portion of the survivin gene promoter was used to drive transcription of a human secreted alkaline phosphatase (SEAP) gene that is transiently transfected into cancer cells and promoter activity is extrapolated from SEAP activity in different cancer cells. Therefore, the instant technical feature does not contribute over prior art.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement may be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To preserve a right to petition, the election must be made with traverse. If the reply

does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANOOP SINGH whose telephone number is (571)272-3306. The examiner can normally be reached on 9:00AM-5:30PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Peter Paras can be reached on (571) 272- 4517. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Anoop Singh/  
Examiner, Art Unit 1632